

Cover Letter

Dear Reviewer,

We are submitting a Microbial Commercialization Activity Notice (MCAN), TS Number: YM95NC, for EPA review. The subject microorganism is a modified strain of *Saccharomyces cerevisiae* that is being developed into a Reference Material (RM) for the National Institute of Standards and Technology (NIST). As the designated metrology institute of the U.S., NIST develops RMs that are well-characterized for specific attributes. See <https://www.nist.gov/srm/about-nist-srms> for more information on NIST RMs. The yeast strain is intended to be used as a qualitative and quantitative material for microbial abundance measurements.

NIST will not be manufacturing the material. Instead, NIST will provide the strain to an external manufacturer who will produce individual vials of lyophilized yeast cells (approximately 10^7 cells per vial). The manufacturer will be awarded the contract following institutional procurement policies. It is not yet known who the manufacturer will be. NIST will then characterize the material for total cells per vial and offer it as NIST RM 8230.

Sincerely,

Tara Eskandari



BIO2018P1

Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038

EPA Biotech Form**Biotech Form Report Number**Mark (X) if anything is CBI ☐

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

I. SUBMITTER IDENTIFICATION INFORMATIONCBI ☐

First Name	Tara	Last Name	Eskandari		
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Ia. JOINT SUBMITTER -- If you are submitting this notice as part of a joint submission, mark (X)

☐CBI ☐

First Name		Last Name			
Position		Company			
Mailing Address (Number & Street)					
City		State		Postal Code	
e-mail			Telephone (include area code)		

II. TECHNICAL CONTACT IDENTIFICATION INFORMATIONCBI ☐

First Name	Nancy	Last Name	Lin		
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e-mail	nancy.lin@nist.gov		Telephone (include area code)	3019754935	



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NON-CBI SUBMISSION

III. TYPE OF SUBMISSION (Check One)

- ☒ MCAN (Microbial Commercial Activity Notice)
☐ TERA (TSCA Experimental Release Application)
☐ Tier I Exemption
☐ Tier II Exemption
☐ Biotech TME (Test Market Exemption)

IV. TEXT / COMMENTSCBI ☐

The submission is for a modified *Saccharomyces cerevisiae* yeast strain that is being developed as a NIST Reference Material (RM). The RM is intended to be used as a qualitative and quantitative material for microbial abundance measurements.



LIST OF ATTACHMENTS

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Mark (X) this box if the data continues on the next page.

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NON-CBI SUBMISSION

Continuation Sheet

ID		Field	